Filed 04/04/2008

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Case 4:08-cv-01831-SBA Document 1

PLEASE TAKE NOTICE that Defendants General Electric Company and GE Healthcare Inc. (hereinafter "the GE Defendants"), by their undersigned attorneys, hereby remove the above-entitled state court action, Case No.: CGC-08-472978, from the Superior Court of the State of California, County of San Francisco, to the United States District Court for the Northern District of California, San Francisco, on the basis of diversity jurisdiction. In support of this Notice of Removal, the GE Defendants state as follows:

#### 1. Introduction

This case is hereby removed from state court to federal court because there is complete diversity between Plaintiffs Carol Moorhouse and James Moorhouse ("Plaintiffs") and all properly named and served Defendants, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare LLC, General Electric Company, GE Healthcare Inc., Covidien, Inc., Mallinckrodt Inc., and Bracco Diagnostics, Inc. (the "Manufacturing Defendants"). The GE Defendants are informed and believe that McKesson Corporation and Merry X-Ray Chemical Corp. (the "Distributor Defendants") are nominal defendants which have been fraudulently joined, and thus, their citizenship is not considered for purposes of determining diversity jurisdiction. Further, the amount in controversy exceeds \$75,000.00. Therefore, this Court has original jurisdiction under 28 U.S.C. § 1332.

#### 2. The State Court Action

On or about March 5, 2008, a civil action was commenced in the Superior Court of the State of California in Sam Francisco County entitled, *Carol Moorhouse and James Moorhouse v. Bayer Healthcare Pharmaceuticals, Inc., et al.*, having been assigned Case No. CGC-08-472878 (San Francisco Super. Ct. March 4, 2008) The Complaint asserts claims for (1) Strict Liability: Failure to Warn (All Defendants); (2) Negligence (All Defendants); (3) Fraud: Misrepresentation (Manufacturing Defendants); (4) Fraud: Concealment, Suppression or Omission of Material Facts (Manufacturing Defendants); and (5) -2-

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Negligent Misrepresentation (Manufacturing Defendants); (6) Violations of 1 Consumer Legal Remedies Act (All Defendants); and (7) Loss of Consortium (All 2 3 Defendants). 4 5 6

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Plaintiffs generally allege that Carol Moorhouse contracted nephrogenic systemic fibrosis ("NSF") as a result of exposure to gadolinium-based contrast agents manufactured by one or more of the named defendants. (See Complaint at ¶¶ 41 through 60.)

#### 3. Pleading and Process

As required by 28 U.S.C. § 1446(a), attached are copies of all state court process, pleadings and orders served upon the GE Defendants in the removed case. (See Exhibit "A.")

(See Plaintiffs' Complaint, attached hereto as Exhibit "A.")

#### 4. The Removal is Timely

The GE Defendants are informed and believe that the first date upon which any named defendant was served with a copy of said Complaint in the removed case was March 6, 2008, when the Defendants were served with a copy of the Summons and Complaint through their registered agent for service of process, CT Corporation System. (See Service of Process Transmittal, attached as Exhibit "A.") Accordingly, this Notice of Removal is filed within 30 days of service upon any defendant and, therefore, is timely under 28 U.S.C. § 1446(b). (See United Computer Sys. v. AT&T Corp., 298 F3d 756, 762 (9<sup>th</sup> Cir. 2002).)

#### Basis for Removal – Diversity Jurisdiction 5.

This is a civil action that falls within the Court's original jurisdiction under 28 U.S.C. § 1332 (diversity of citizenship), and is one which may be removed to this Court by the GE Defendants pursuant to the provisions of 28 U.S.C. § 1441 in that it is a civil action between citizens of different states and the matter in controversy exceeds the sum of \$75,000, exclusive of interest and costs.

#### Amount in Controversy 6.

The amount in controversy for this matter exceeds \$75,000, a. - 3 -

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exclusive of interest and costs. (See 28 U.S.C. § 1332.) California law prohibits Plaintiffs from stating in their Complaint the amount of damages claimed. (See Cal. Code of Civil Procedure § 425.10 (b) (specific amount of damages in personal injury or wrongful death action may not be stated in complaint).) Nevertheless, removal is proper because a fair reading of the Complaint shows that the amount in controversy requirement has been met. (See Kenneth Rothchild Trust v. Morgan Stanley Dean Witter, 199 F.Supp.2d 993 (C.D. Cal. 2002).)

- b. Where a plaintiff's complaint does not specify the amount of damages being sought, whether or not the amount in controversy exceeds jurisdictional limits, can be ascertained from the complaint. (See Singer v. State Farm Mut. Auto Ins. Co., 116 F.3d 373, 376 (9th Cir. 1997). This burden can easily be met if it is facially apparent from the allegations in the complaint that the plaintiff's claims exceed \$75,000.00. (See Kenneth Rothchild Trust v. Morgan Stanley Dean Witter, 199 F.Supp.2d at 998; see also Campbell v. State Farm Mut. Auto Ins. Co., No. CV87-7759 JMI (GHKx), 1988 U.S. Dist. LEXIS 19496, 2-3 (C.D. Cal. 1988) ("For removal purposes, the amount in controversy is to be determined by the allegations in the complaint or where they are not dispositive, by allegations in the petition for removal"); Davenport v. Procter & Gamble Mfg. Co., 241 F2d 511 (2<sup>nd</sup> Cir. 1957).)
- Plaintiffs allege that Mrs. Moorhouse has contracted NSF as a c. result of exposure to gadolinium-based contrast agents. (See Complaint at ¶ 1.) Plaintiffs also allege that NSF is "a progressive disease for which there is no known cure" which causes "thickening, tightening and swelling of the skin" and can cause progress to "a fibrotic or scarring condition of other body organs" (Complaint at ¶ 42.) As a result, Plaintiffs allege that Mrs. Moorhouse has sustained physical injuries from the effects of NSF, as well as pain, suffering and emotional distress. (See Complaint at Prayer No. 2.) For these alleged injuries, Plaintiffs seek special and general damages for past and future medical expenses, lost income, emotional 4849-5600-9730.1

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distress, loss of enjoyment of life and loss of consortium. (See Complaint at Prayer
Nos. 2 and 3.) Plaintiffs also seek punitive damages because they claim that the
Defendants' conduct was "vile, base, willful, malicious, wanton, oppressive and
fraudulent." (Complaint at ¶ 73.)

- Based on these allegations, the alleged damages involved, and d. on the experience of the undersigned counsel and Defendants in pharma-products liability and products cases, the amount in controversy exceeds the sum of \$75,000.00. (See Gebbia v. Wal-Mart Stores, Inc., 233 F.3d 880, 883-884 (5th Cir. 2000) (damages in slip-and-fall case for "medical expenses, physical pain and suffering, mental anguish and suffering, loss of enjoyment of life, loss of wages and earning capacity, and permanent disability and disfigurement" met the jurisdictional threshold); Luckett v. Delta Airlines, Inc., 171 F.3d 295, 298 (5th Cir. 1999) (removal proper where it is facially apparent that amount in controversy exceeds \$75,000); Allison v. Security Benefit Life Ins. Co., 980 F.2d 1213, 1215 (8th Cir. 1992) (punitive damages are properly considered in calculating the amount in controversy).
- A fair reading of these allegations reveals that the alleged damages involved are substantial and exceed \$75,000.00, exclusive of interest and costs, and that this case meets the jurisdictional requirement.

#### Citizenship of the Parties 7.

The requisite complete diversity of citizenship exists between Plaintiffs and all properly named and served Defendants. (See 28 U.S.C. §1332.)

The GE Defendants are informed and believe that Plaintiffs are now and were at the time of filing of the Complaint residents of the state of California. (See Complaint at ¶ 1.) Plaintiffs are therefore California citizens for purposes of federal diversity jurisdiction. (See 28 U.S.C. § 1332(a); Kanter v. Warner-Lambert Co., 265 F.3d 853, 857 (9th Cir. 2001).

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- b. The GE Defendants are informed and believe that Bayer HealthCare Pharmaceuticals, Inc. (Manufacturing Defendant) is a Delaware business entity with its principal place of business in New Jersey. (See Complaint at ¶ 5.) Bayer HealthCare Pharmaceuticals, Inc. was a citizen of the States of Delaware and New Jersey at the time of the filing of the Complaint for purposes of federal diversity jurisdiction (See Exhibit "B," Defendants Bayer Pharmaceuticals Inc. and Bayer Healthcare LLC's Consent to Removal of Action.)
- c. The GE Defendants are informed and believe that Bayer Healthcare LLC (Manufacturing Defendants) is now and was a Delaware business entity with its principal place of business in New York. (See Complaint ¶ 3.) Bayer Healthcare LLC was a citizen of the States of Delaware and New York at the time of the filing of the Complaint for purposes of federal diversity jurisdiction. (See Exhibit "B," Defendants Bayer Pharmaceuticals Inc. and Bayer Healthcare LLC's Consent to Removal of Action.)
- d. General Electric Company (Manufacturing Defendant) is now and was a New York business entity with its principal place of business in the State of Connecticut. (See Complaint at ¶ 9.) General Electric Company was a citizen of the States of New York and Connecticut at the time of the filing of the Complaint for purposes of federal diversity jurisdiction.
- e. GE Healthcare Inc. (Manufacturing Defendant) is now and was a Delaware corporation with its principal place of business in the State of New Jersey. (See Complaint at ¶11.) GE Healthcare Inc. was a citizen of the States of Delaware and New Jersey at the time of the filing of the Complaint for purposes of federal diversity jurisdiction.
- f. The GE Defendants are informed and believe that Defendant Mallinckrodt Inc. (Manufacturing Defendant) is now and was a Delaware entity with its principal place of business in Missouri (See Complaint at ¶ 17.) Mallinckrodt Inc. was a citizen of the States of Delaware and Missouri at the time 4849-5600-9730.1

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of the filing of the Complaint for purposes of federal diversity jurisdiction. (See Exhibit "C," Declaration of Thomas A. Woods at ¶ 4.)

- The GE Defendants are informed and believe that Defendant Covidien Inc. (Manufacturing Defendant) is now and was a Delaware corporation with its principal place of business in New Hampshire. (See Complaint at ¶ 14.) Covidien Inc. is neither incorporated in, nor maintains its principal place of business in California. (See Exhibit "C," Woods Decl. at ¶ 3.)
- h. The GE Defendants are informed and believe that Defendant Bracco Diagnostics, Inc. (Manufacturing Defendant) is now and was a Delaware entity with its principal place of business in New Jersey. (See Complaint at ¶ 21.) Bracco Diagnostics, Inc. was a citizen of the States of Delaware and New Jersey at the time of the filing of the Complaint for purposes of federal diversity jurisdiction. (See Exhibit "D," Declaration of Aggie Lee at ¶ 4.)
- i. The GE Defendants are informed and believe that McKesson Corporation (Distributing and Nominal Defendant) is now and was a Delaware corporation with its principal place of business in the State of California. (See Complaint at ¶ 30.) McKesson, however, is fraudulently joined, and therefore, its citizenship is disregarded for purposes of determining federal diversity jurisdiction. (See Morris v. Princess Cruises, Inc., 236 F.3d 1061, 1067 (9th Cir. 2001).) (See Paragraphs 9(a) through 9(k), *infra*.)
- The GE Defendants are informed and believe that Defendant Merry X-Ray Chemical Corporation (Distributing and Nominal Defendant) is now and was a California Corporation with its principal place of business in the State of California. (See Complaint at ¶ 33.) Merry X-Ray, however, is fraudulently joined, and therefore, its citizenship is disregarded for purposes of determining federal diversity jurisdiction. (See Morris v. Princess Cruises, Inc., 236 F.3d at 1067.) (See Paragraphs 9(a) through 9(k), *infra*.)

### 8. Fraudulent Joinder Standard for Non-Diverse Defendants

a. In determining whether there is federal jurisdiction, a federal court normally will examine the plaintiff's case and not the defendant's pleadings. However, when considering whether there is a fraudulent joinder, the court "will go somewhat further" because "the defendant seeking removal to the federal court is entitled to present the facts showing the joinder to be fraudulent." (*Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9<sup>th</sup> Cir. 1998) (internal citations omitted).) A federal court may disregard a non-diverse defendant for the purposes of determining diversity if that federal court determines that the non-diverse defendant's joinder is "fraudulent" or a "sham" because no cause of action has been stated against that defendant under state law. (See *Morris v. Princess Cruises, Inc.*, 236 F.3d at 1067.)

b. Fraudulent joinder exists "when there is no possibility of recovery against a resident defendant 'according to the settled rules of the state'." (TPS Utilicom Services, Inc., 223 F.Supp.2d 1089, 1102 (C.D. Cal. 2002).) While the test for fraudulent joinder resembles a Rule 12(b)(6) analysis in that the federal court accepts non-conclusory allegations as true, the Court's inquiry is broader than Rule 12(b)(6). (Id.)

c. A defendant is fraudulently joined where there is no *reasonable* basis in fact for a claim against it. (See *Maffei v. Allstate Ins. Co.*, 412 F. Supp. 2d 1049, 1053 (E.D. Cal. 2006) (citing *Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921) (joinder was fraudulent where defendant had 'no real connection [to] the controversy' because the allegations against the defendant were 'without any reasonable basis in fact').)

### 9. Fraudulent Joinder of Distributor Defendants

a. The citizenship of distributor defendants McKesson and Merry X-Ray should be disregarded for the purposes of determining jurisdiction under 28 U.S.C. § 1332 and 28 U.S.C. § 1441(b), because there is no reasonable basis in fact - 8 -

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for establishing liability against the distributor defendants (and thus, the distributor
defendants were fraudulently joined.) The presence of a sham or nominal party will
not defeat removal on diversity grounds. (See Strotek Corp. v. Air Transport
Assoc., 300 F.3d at 1131.)

- b. The Complaint fails to establish a factual nexus between the Distributor Defendants and Mrs. Moorhouse's injuries. In addition, none of the claims musters a reasonable basis for liability. Plaintiffs allege three causes of action against the Distributor Defendants: (1) strict liability: failure to warn; (2) negligence; (3) CLRA violations and (4) loss of consortium. However, "[i]f the plaintiff[s] fail to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state, the joinder of the resident defendant is fraudulent." (*McCabe v. Gen. Foods Corp.*, 811 F.2d 1336, 1339 (9<sup>th</sup> Cir. 1987).
- On the face of the Complaint, the liability if any, of the c. Distributor Defendants is derivative of the claims against the Manufacturer Defendants, and no reasonable basis exists for obtaining independent relief against the Distributor Defendants. Plaintiffs' claims are based entirely upon the alleged knowledge and conduct of the Manufacturing Defendants. Specially, it is alleged that the Manufacturing Defendants "never tested the safety of their gadoliniumbased contrast agents in individuals with kidney impairment;" that "it was not until September 2007 that [Manufacturing Defendants] Bayer, GE, Bracco, and Mallinckrodt finally sent letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who received MRIs using gadolinium-based contrast agents" (emphasis supplied); and that had Mrs. Moorhouse and her healthcare providers been warned about the risks associated with these agents, she would not have been administered these agents and "would not have been afflicted with NSF." (See Complaint at ¶¶ 46 and 56-57.) Indeed, the gravamen of the Complaint is the actions which occurred prior to sale and distribution of the 4849-5600-9730.1

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products at issue. "In pre-clinical studies during which gadolinium-based contrast
agents were injected into laboratory animals, consistent pattern of toxicity including
nephrogenic fibrotic changes in the kidneys and other body organs occurred."
(Complaint at ¶ 48) (emphasis added). Since Merry X-Ray and McKesson are
distributors, a priori, they could not have been involved in these products at any
pre-clinical stage of product development.

- d. The Complaint is devoid of any individualized or independent conduct for which the Distributor Defendants have been named in this action. (See Complaint, generally.) Instead, plaintiffs lump the Distributor Defendants with the Manufacturing Defendants -- i.e., "Defendants" knew or should have known that the use of gadolinium contrast agents created a risk of serious bodily injury and death in patients with impaired kidney function; that "Defendants" failed to warn Mrs. Moorhouse and her prescribing physicians about the serious health risk associated with gadolinium-based contrast agents; and that "Defendants" have repeatedly failed to advise consumers and/or their healthcare providers of the causal relationship between gadolinium-based contrast agents to individuals with impaired kidney function. (See Complaint at ¶¶ 52-53 and 55.)
- e. Plaintiffs' failure to allege an independent basis for liability against the Distributor Defendants is not surprising because the Distributing Defendants' only function was to distribute gadolinium-based contrast agents to imaging facilities. (See Exhibit "E," Declaration of Greg Yonko, and Exhibit "F," Declaration of Larry Lawson.) Plaintiffs have not and cannot allege in their Complaint that the Distributor Defendants designed, manufactured, marketed or administered any gadolinium-based contrast agents. Plaintiffs have not and cannot allege in their Complaint that the Distributing Defendants designed, assembled or otherwise provided any of the packaging, labels or warnings for any gadolinium-based contrast agents.

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f. Indeed, Defendant Merry X Ray has never designed,
manufactured, marketed or administered any of the Gadolinium-based contrast
agent product lines. (See Lawson Decl. at ¶ 2.) Merry X Ray is engaged in the
business of distributing and selling various medical products, and specifically with
respect to Gadolinium-based contrast agents, its role in the chain of distribution is,
and has always been, to sell this product line to various imaging facilities in the
same packaging in which it was received from the manufacturer. (See Lawson
Decl. at ¶¶ 2-3.) Merry X Ray does not, and did not, design or assemble or
otherwise provide any of the packaging, labels or warnings for this product line,
and does not, and did not, design, test, manufacture, label or market any of this
product line and has never distributed MRI or MRA machines. (See Lawson Decl.
at ¶¶ 2-3.)

- McKesson designed, Likewise, Defendant has never g. manufactured, marketed or administered any of the gadolinium-based contrast agent product lines. (See Yonko Decl. at ¶¶ 2-3.) McKesson is engaged in the business of distributing and selling various medical products, and specifically with respect to Gadolinium-based contrast agents, its role in the chain of distribution is, and has always been, to sell this product line to various imaging facilities in the same packaging in which it was received from the manufacturer. (See Yonko Decl. at ¶¶ 2-3.) McKesson does not, and did not, design or assemble or otherwise provide any of the packaging, labels or warnings for this product line, and does not, and did not, design, test, manufacture, label or market any of this product line, and has never distributed MRI or MRA machines. (See Yonko Decl. at ¶ 2-3.)
- Failure to allege a factual basis for asserting a claim against the h. Distributor Defendants renders them fraudulently joined. (See TPS Utilicom Servs, Inc. v. AT &T Corp., 223 F.Supp.2d at 1102-04) (holding that the plaintiff fraudulently joined two defendants when it failed to allege conduct of those "defendants that would satisfy the conduct element of either claim.")

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i. Strict Liability: Failure to Warn: Plaintiffs maintain that the Distributor Defendants are strictly liable for failure to warn (See Complaint at ¶¶ 66, 67.) This claim fails because the Distributor Defendants had no duty to warn Plaintiffs. Although the general rule is that all parties in the chain of distribution can be strictly liable for failure to warn claims, Anderson v. Owens-Corning Fiberglass Corp., 53 Cal.3d 987, 994 (1991), under California law, a distributor has no duty to warn the ultimate consumer when there is no effective way to convey the warning. (See *Perssons v. Saloman N. Am., Inc.*, 217 Cal.App.3d 168, 178 (1990).) Here, the Distributor Defendants could not communicate warnings to consumers because, under Food and Drug Administration (FDA) regulations, the Distributor Defendants would violate federal law if it altered or added to the Manufacturing Defendants' warning labels. (See 21 U.S.C. §§ 331, 332 and 333.) Because the Distributor Defendants had no duty to warn Plaintiffs about any risks associated with the gadolinium-based contrast agents, and indeed would violate federal law by doing so, they cannot be found liable in strict liability for failure to warn. (See Perssons, 217 Cal. App. 3d at 178.) Indeed, there is no legal precedent in California to support a finding of liability for failure to warn against distributors in the prescription drug context.

i. Negligence: Plaintiffs maintain that the Distributor Defendants were negligent because they breached a duty to exercise reasonable care in the "design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution" of both the contrast agents at issue and the MRI and MRA machines designed to be used in conjunction therewith. (See Complaint at ¶¶ 69-72.) As with their strict liability claim, the Distributor Defendants could not be liable under any of these theories, because the Distributor Defendants did not design, test, manufacture, label or market any of the products at issue and in addition, had no role at all in the chain of distribution of the MRI and MRA machines themselves. (See Lawson Decl. at ¶¶ 2-3; see Yonko Decl. at ¶¶ 2-3. Thus, the Distributor 4849-5600-9730.1

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Defendants had no duty to the Plaintiffs for failure to do so with reasonable care.

k. Violations of the Consumer Legal Remedies Act: Plaintiffs maintain that the Distributor Defendants are liable for violations of California consumer protection statutes codified in Cal. Civil Code § 1750, et seq. ("CLRA"). As with their strict liability claim, the Distributor Defendants could not be liable under the CLRA because they did not label or market any of the products at issue and because the CLRA does not apply to prescription drugs, medical devices or other pharmaceutical products which are provided to the consumer indirectly by way of prescription.

- The CLRA has been in existence since 1970, yet no (1) published decision has ever held that the CLRA is applicable to a prescription drug, medical device or pharmaceutical product. The CLRA was enacted in response to violence and rioting in the late 1960's and was designed to protect consumers from the sale of goods by disreputable retailers who charged exorbitant prices or offered inferior goods for sale, particularly to individuals in low-income areas or with lower credit scores. (See Berry v. American Exp. Publishing, Inc. (2007) 147 Cal. App. 4th 224, 230.)
- By definition, the CLRA does not apply to the products at (2) issue in this case. The CLRA enumerates all of the "proscribed practices" for which a violation can be found. The list is exhaustive and applies only to practices undertaken in connection with "the sale or lease of goods or services to any consumer." (See Cal. Civil Code § 1770(a).) "Goods" is defined as "tangible chattels bought or leased for use primarily for personal, family, or household purposes . . . . " (See Cal. Civil Code § 1761(a).) The Gadolinium-based contrast agents at issue in this case are not "goods" as that term is defined and were not sold directly to the Plaintiffs. Moreover, there is no allegation that the Distributor Defendants contracted with the Plaintiffs for any provision of services under the

See Cal. Civil Code § 1750.

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CLRA. Thus, no CLRA cause of action lies against the Distributor Defendants.

- between consumer products to which the CLRA applies and the pharmaceutical agents at issue here. (See *Cattie v. Wal-mart Stores, Inc.*, 504 F.Supp.2d 939 (S.D. Cal. 2007) (deceptive advertising claim for on-line sale of bed linens to consumers); *Laster v. T-Mobile USA, Inc.* (deceptive advertising claim for sale of cell phones to consumers); *Outboard Marine Corp. v. Superior Court* (1975) 52 Cal.App.3d 30 (concealment claim for sale of off-road vehicle to consumers); *Farm Raised Salmon Cases* (2008) 42 Cal.4<sup>th</sup> 1077 (artificial coloring of salmon sold by grocery store to consumers); and *Von Grabe v. Spring PCS*, 312 F.Supp.2d 1285 (S.D. Cal. 2003) (deceptive business practices claim arising out of sale of cell phone and charger to consumer).)
- (4) Plaintiffs' CLRA claims are also jurisdictionally barred due to violation of the statutory notice requirements. Plaintiffs' failure to comply with the notice provisions requires dismissal of the cause of action with prejudice. (See Laster v. T-Mobile USA, Inc., 407 F.Supp.2d at 1195-96; Von Grabe v. Spring PCS, 312 F.Supp.2d at 1304; Cattie v. Wal-Mart Stores, Inc., 504 F.Supp.2d 939.) Section 1782 of the Cal. Civil Code mandates that 30 days before commencing an action for damages, the plaintiff must "[n]otify the person alleged to have employed or committed methods, acts, or practices declared unlawful by Section 1770 of the particular alleged violations of 1770." (Cal. Civil Code § 1782 (a)(1).) The notice provisions of the CLRA are jurisdictional and must be applied literally. (See Outboard Marine Corp. v. Superior Court (1975) 52 Cal.App.3d 30.) Plaintiffs' Complaint seeks both injunctive relief and damages, including restitution and attorneys' fees, and thus, the notice requirements of the CLRA apply. (See Complaint at ¶ 98.)

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### 1. Loss of Consortium Claim

Under California law, a claim for loss of consortium is deemed to be derivative of all other claims asserted in the case. (See *Rodriquez v. Bethlehem Steel Corp.* (1974) 12 Cal.3d 382.) Thus, despite a loss of consortium claim's independent existence, entitlement to recover is based on the injured plaintiff's right to recover. Accordingly, the Seventh Cause of Action for loss of consortium fails for all the reasons sets forth above. Since there is no viable cause of action for strict liability, negligence or CLRA against the Distributor Defendants, there is no viable cause of action for loss of consortium against the Distributor Defendants either.

### 10. Consent and Joinder of Defendants

All properly served defendants have consented to this removal, and have joined by signing this notice of removal. (See Exhibits B, C and D.) Defendants are not required to gain the consent of any defendants who have not been properly named or served. (See *Salveson v. W. States Bankcard Ass'n*, 731 F.2d 1423, 1429 (9<sup>th</sup> Cir. 1984) (holding that the Ninth Circuit rule is that "a party not served need not be joined" in a notice of removal); see also *Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1193 (9<sup>th</sup> Cir. 1988).) In the event that such service has occurred, no consent is required. Fraudulently joined parties need not join in or consent to a notice of removal. (See *United Computer Sys. v. AT&T Corp.*, 298 F.3d 756, 762 (9<sup>th</sup> Cir. 2002).)

### 11. Notice Given

Pursuant to 28 U.S.C. § 1446(d), Defendants are filing this Notice of Removal concurrently with the State Court in which the action is currently pending. In addition, Notice of Filing Notice of Removal was served concurrently on Plaintiffs' counsel.

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#### 12. Venue

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The United States District Court of the Northern District of California. San Francisco, embraces the county in which the State Court action is now pending and, therefore, this Court is a proper venue for this action. 28 U.S.C. §§ 84(c)(1), 1441(a).

#### Additional Discovery, Briefing, and Argument 13.

If any question arises as to the propriety of this removal, the GE Defendants request the opportunity to conduct discovery or brief any disputed issues and to present oral argument in support of their position that this case is properly removable.

#### Non-Waiver of Defenses 14.

Nothing in this Notice of Removal or related documents shall be interpreted as a waiver or relinquishment of Defendants' right to assert any defense or affirmative matter in this proceeding.

#### 15. Conclusion

Accordingly, the GE Defendants respectfully requests that this action now pending against Defendants in the Los Angeles County Superior Court, be removed to this Court and that this action be placed upon the docket of this Court for further proceedings as though originally instituted in this Court.

Dated: April 4, 2008 KUTAK ROCK LLP

Stephanie A. Hingle Attorneys for Defendants

NERAL ELECTRIC COMPANY and GE HEALTHCARE INC.

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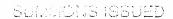
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# **EXHIBIT "A"**

### IMAGED

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Lawrence J. Gomick (SBN 136290) Debra DeCarli (SBN 237642)

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Attorneys for Plaintiffs

DEPARTMENT 212

#### SUPERIOR COURT OF CALIFORNIA, UNLIMITED JURISDICTION

#### COUNTY OF SAN FRANCISCO

CAROL MOORHOUSE and JAMES MOORHOUSE,

Plaintiffs,

VS.

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC; GENERAL ELECTRIC COMPANY; GE HEALTHCARE, INC.; + COVIDIEN, INC.; MALLINCKRODT, INC.; BRACCO DIAGNOSTICS, INC.; McKESSON CORPORATION; MERRY X-RAY CHEMICAL CORP.; and DOES 1 through 35

Defendants.

Case No:

CEC-98 -472978

#### COMPLAINT FOR DAMAGES DUE TO:

- 1) STRICT LIABILITY: FAILURE TO WARN (All Defendants);
- NEGLIGENCE (All Defendants):
- 3) FRAUD: MISREPRESENTATION (Manufacturing Defendants);
- FRAUD: CONCEALMENT, SUPPRESSION OR OMISSION OF MATERIAL FACTS (Manufacturing Defendants);
- 5) NEGLIGENT MISREPRESENTATION (Manufacturing Defendants);
- 6) VIOLATION OF CONSUMER LEGAL REMEDIES ACT (All Defendants); and
- 7) LOSS OF CONSORTIUM (All Defendants)

Plaintiffs, Carol Moorhouse and James Moorhouse, (hereinafter "Plaintiffs") allege as follows:

#### **PARTIES**

#### Plaintiffs

Carol Moorhouse ("Mrs. Moorhouse") and her husband, James Moorhouse ("Mr. Moorhouse"), are residents of the State of California. Mrs. Moorhouse has nephrogenic systemic fibrosis ("NSF"). NSF is an incurable, painful and deadly disease. Mrs. Moorhouse contracted NSF as a result of receiving MRIs and MRAs using intravenous injections of gadolinium-based contrast agents.

#### Manufacturing Defendants

Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Healthcare LLC (jointly referred to as "Bayer") manufacture, market and sell Magnevist, a gadolinium-based contrast agent that, on

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information and belief, was injected into Plaintiff.

Defendant Bayer HealthCare LLC, a division of Bayer AG, is a Delaware business entity with its principal place of business in New York.

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4. Bayer HealthCare LLC is duly authorized to conduct business in the State of California and does business in San Francisco County.

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5. Defendant Bayer HealthCare Pharmaceuticals, Inc. is a Delaware business entity with its principal place of business in New Jersey. Defendant Bayer HealthCare Pharmaceuticals, Inc. is the U.S.based pharmaceuticals unit of Bayer Healthcare LLC.

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Bayer HealthCare Pharmaceuticals, Inc. is duly authorized to conduct business in the State of California and does business in San Francisco County.

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At all times relevant to this complaint, Baver advertised, promoted, and sold Magnevist in San Francisco County.

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Defendants General Electric Company and GE Healthcare, Inc. (jointly referred to as "GE") manufacture and sell Omniscan, a gadolinium-based contrast agent that, on information and belief, was injected into Mrs. Moorhouse.

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Defendant General Electric Company is a New York business entity with its principal place of business in Connecticut.

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General Electric Company is duly authorized to conduct business in the State of California

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and does business in San Francisco County. 11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of

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business in New Jersey.

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GE Healthcare, Inc. is duly authorized to conduct business in the State of California and does business in San Francisco County.

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At all times relevant to this complaint, GE advertised, promoted, and sold Ornniscan and its MRI and MRA machines in San Francisco County.

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Defendants Covidien, Inc. and Mallinckrodt, Inc. (jointly referred to as "Covidien") manufacture, distribute and sell OptiMARK, a gadolinium-based contrast agent that, on information and belief, was injected into Mrs. Moorhouse.

	15.	Defendant Covidien, Inc. is a D	elaware co	orporation v	vith its	principal	place o	of busines:	s in
New Ha	mpshir	re.							

- Covidien, Inc. is duly authorized to conduct business in the State of California and does 16. business in San Francisco County.
- Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business 17. in Missouri. Mallinckrodt is a business unit of Covidien, Inc.
- Mallinckrodt, Inc. is duly authorized to conduct business in the State of California and does business in San Francisco County.
- At all times relevant to this complaint, Covidien advertised, promoted, and sold OptiMARK in San Francisco County.
- Defendant Bracco Diagnostics, Inc. ("Bracco") manufactures, sells and distributes MultiHance and ProHance, gadolinium-based contrast agents that, on information and belief, were injected into Mrs. Moorhouse.
- Bracco Diagnostics, Inc. is a Delaware corporation with its principal place of business in 21. New Jersey.
- Bracco Diagnostics, Inc. is duly authorized to conduct business in the State of California 22. and does business in San Francisco County.
- At all times relevant to this complaint, Bracco advertised, promoted, and sold MultiHance 23. and ProHance in San Francisco County.
- The true names and capacities of those Defendants designated as Does 1-15 are unknown to Plaintiffs. Plaintiffs allege on information and belief that Does 1-15 manufactured gadolinium-based contrast agents that were injected into Mrs. Moorhouse and/or manufactured MRI and MRA machines with which MRIs and/or MRAs were performed on Mrs. Moorhouse using gadolinium-based contrast agents. Plaintiffs allege on information and belief that each of these fictitiously named defendants bears legal responsibility for the events and damages set forth in this complaint.
- Plaintiffs allege on information and belief that Does 1-15 were and are companies 25. authorized to do and doing business in the State of California and have regularly conducted business in the County of San Francisco, State of California.

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- 26, Plaintiffs will amend this Complaint to show the identity of each fictitiously named Defendant when they have been ascertained.
- The Bayer, GE, Covidien and Bracco Defendants, along with Does 1-15, are collectively 27. referred to as the Manufacturing Defendants.

#### Distributor Defendants

- Defendant McKesson Corporation distributes Omniscan and, on information and belief, 2.8 other gadolinium-based contrast agents. Plaintiffs allege on information and belief that McKesson distributed the Omniscan and/or other gadolinium-based contrast agents that were injected into Mrs. Moorhouse.
- 29. Defendant McKesson Corporation is a Delaware corporation with its principal place of business at One Post Street, San Francisco, California.
- 30. McKesson Corporation is duly authorized to conduct business in the State of California and does business in San Francisco County,
- 31. At all times relevant to this complaint, on information and belief, McKesson sold Omniscan and/or other gadolinium-based contrast agents in San Francisco County.
- 32. Defendant Merry X-Ray Chemical Corporation distributes Magnevist and/or other gadolinium-based contrast agents. Piaintiffs allege on information and belief that Merry X-Ray distributed the Magnevist and/or other gadolinium-based contrast agents that were injected into Mrs. Moorhouse.
- 33. Defendant Merry X-Ray Chemical Corporation is a California corporation with its principal place of business at 4444 Viewridge Avenue, San Diego, California.
- Merry X-Ray Chemical Corporation is duly authorized to conduct business in the State of 34 California and does business in San Francisco County.
- At all times relevant to this complaint, Merry X-Ray sold Magneyist and/or other gadolinium-based contrast agents in San Francisco County.
- The true names and capacities of those Defendants designated as Does 16-35 are unknown to Plaintiffs. Plaintiffs allege on information and belief that Does 16-35 distributed gadolinium-based contrast agents that were injected into Plaintiff Carol Moorhouse. Plaintiffs allege on information and belief that each of these fictitiously named Defendants bears legal responsibility for the events and

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damages set forth in this Complaint.

- Plaintiffs allege on information and belief that Does 16-35 were and are companies authorized to do and doing business in the State of California and have regularly conducted business in the County of San Francisco, State of California.
- Plaintiffs will amend this Complaint to show the identity of each fictitiously named 38. defendant when they have been ascentained.
- McKesson and Merry X-Ray, along with Does 16-35, are collectively referred to as the 39. Distributor Defendants.
- The Manufacturing Defendants and the Distributor Defendants are collectively referred to 40. as Defendants.

#### **FACTS**

- Mrs. Moorhouse was diagnosed with NSF in or around May of 2007. 41.
- NSF is predominantly characterized by discoloration, thickening, tightening, and swelling 42. of the skin after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF is a progressive disease for which there is no known cure.
- NSF is a man-made disease. It only occurs in patients who have received a gadoliniumbased contrast agent for an MRI or an MRA.
- Gadolinium is a highly toxic heavy metal. It does not occur naturally in the human body. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent.
- 45. Because gadelinium is toxic, it has to be coated to keep it from coming in contact with human tissue when used in connection with MRIs or MRAs. This coating process is called chelation.

COMMINIMENT DANGER AND BIRY DEMAND

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- Gadolinium is eliminated from the body by the kidneys. Gadolinium-based contrast agents 46. are not safe if the chelate separates from the gadolinium, which is what happens over time if kidneys are not functioning properly. Individuals with impaired kidney function risk dechelation and cannot efficiently or quickly eliminate gadolinium from their bodies. The Manufacturing Defendams never tested the safety of their gadolinium-based contrast agents in individuals with kidney impairment.
- On information and belief, the gadolinium-based contrast agents injected into Mrs. 47. Moorhouse were manufactured by the Manufacturing Defendants and distributed by the Distributor Defendants.
- 48. In pre-clinical studies during which gadolinium-based contrast agents were injected into laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the kidneys and other body organs occurred.
- During the years that Defendants have manufactured, marketed, distributed, sold and 49. administered gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, and other clinical data that have described and/or demonstrated NSF in connection with the use of gadolinium-based contrast agents.
  - 50. Mrs. Moorhouse received MRIs and/or MRAs utilizing gadolinium-based contrast agents.
- 51. Mrs. Moorhouse had impaired kidney function at the time she received her first injection of gadolinium-based contrast agent and continued to have impaired kidney function at the time she received each subsequent injection of gadolinium-based contrast agent.
- 52. During the time period when Mrs. Moorhouse received injections of the Manufacturing Defendants' gadolinium-based contrast agents, Defendants knew or should have known that the use of gadolinium-based contrast agents created a risk of serious bodily injury and death in patients with impaired kidney function.
- Defendants failed to warn Mrs. Moorhouse and her healthcare providers about the serious health risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives.
- As a direct and proximate result of receiving injections of gadolinium-based contrast agents manufactured, distributed, sold and/or administered by Defendants, Mrs. Moorhouse developed NSF.

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- Defendants have repeatedly and consistently failed to advise consumers and/or their 55. healthcare providers of the causal relationship between gadolinium-based contrast agents and NSF in patients with renal insufficiency. Defendants knew or should have known of the risk of NSF posed by gadolinium-based contrast agents to individuals with impaired kidney function years before they finally issued warnings.
- It was not until September 2007 that Bayer, GE, Brecco and Mallinckrodt finally sent 56. letters to healthcare providers warning them of the risk of NSF to kidney impaired individuals who received MRIs using gadolinium-based contrast agents.
- Had Mrs. Moorhouse and/or her healthcare providers been warned about the risks associated with gadolinium-based contrast agents, she would not have been administered gadolinium-based contrast agents and would not have been afflicted with NSF.
- As a direct and proximate result of Mrs. Moorhouse being administered gadolinium-based contrast agents, she has suffered severe physical injury and pain and suffering, including, but not limited to, the effects of NSF. Mrs. Moorhouse's physical injuries and pain and suffering will inevitably worsen over time and will in all likelihood lead to death.
- 59. As a direct and proximate result of being administered gadolinium-based contrast agents, Plaintiffs suffered and continue to suffer significant mental anguish and emotional distress and will continue to suffer significant mental anguish and emotional distress in the future.
- As a direct and proximate result of being administered gadolinium-based contrast agents, 60. Plaintiffs have also incurred medical expenses and other economic damages and will continue to incur such expenses in the future.

#### DISCOVERY RULE & FRAUDULENT CONCEALMENT

The discovery rule should be applied to toll the running of the statute of limitations until 61. Plaintiffs knew or through the exercise of reasonable care and diligence should have known of the existence of their claims against all Defendants. The nature of Plaintiffs' injuries and darnages, and their relationship to gadolinium-based contrast agents used in conjunction with MRIs and MRAs, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiffs, until a time less than two years before the filing of this Complaint. Therefore, under appropriate

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application of the discovery rule	e, Plaintiffs	' suit was	filed	well within	the applicable	statutory	limitations
period.							

Defendants are estopped from asserting a statute of limitations defense because all 62. Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and all Defendants' tortious conduct.

#### FIRST CAUSE OF ACTION

(Against All Defendants)

### STRICT LIABILITY: FAILURE TO WARN

- Plaintiffs incorporate by reference and reallege each paragraph set forth above. 63.
- Defendants' gadolinium-based contrast agents, and MRI and MRA machines designed to 64. be used in conjunction with gadolinium-based contrast agents, were defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that their products created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.
- Because of Defendants' failure to provide adequate warnings with their products, Mrs. 65. Moorhouse was injected with gadolinium-based contrast agents which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Those gadolinium-based contrast agents are the legal cause of Mrs. Moorhouse's serious physical injuries, harm, damages and economic loss. Mrs. Moorhouse will continue to suffer such harm, damages and economic loss in the future.

#### SECOND CAUSE OF ACTION

(Against All Defendants)

#### NEGLIGENCE

- 66. Plaintiffs incorporate by reference and reallege each paragraph set forth above.
- Defendants had a duty to exercise reasonable care in the design, formulation, testing, 67. manufacture, labeling, marketing, sale and/or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm

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and adverse events.

- Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, 68. testing, marketing, or distribution of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents in that they knew or should have known that the products could cause significant bodily harm or death and were not safe for use by certain types of consumers.
- Defendants failed to exercise ordinary care in the labeling of gadolinium-based contrast 69. agents and the labeling of MRI and MRA machines designed to be used in conjunction with gadoliniumbased contrast agents and failed to issue to consumers and their health care providers adequate warnings concerning the risks of serious bodily injury or death due to the use of gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents.
- Despite the fact that Defendants knew or should have known that gadolinium-based 70. contrast agents and the MRI and MRA machines designed to be used in conjunction with gadoliniumbased contrast agents posed a serious risk of bodily harm to consumers, Manufacturing and Distributor Defendants unreasonably continued to manufacture and market gadolinium-based contrast agents and the MRI and MRA machines designed to be used in conjunction with gadolinium-based contrast agents for administration to MRI and MRA patients with renal insufficiency and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.
- At all relevant times, it was foreseeable to Defendants that consumers like Mrs. Moorhouse would suffer injury as a result of their failure to exercise ordinary care as described above.
- As a direct and proximate result of Defendants' negligence, Mrs. Moorhouse has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiffs and other users of Defendants' products, and for the primary purpose of increasing Desendants' profits. As such, Plaintiffs are entitled to exemplary damages.

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#### THIRD CAUSE OF ACTION

(Against Manufacturing Defendants)

#### FRAUD

- Plaintiffs incorporate by reference and reallege each paragraph set forth above. 74.
- Manufacturing Defendants knowingly and intentionally made materially false and 75. misleading representations to Mrs. Moorhouse's healthcare providers and to the public, to the effect that gadolinium-based contrast agents were safe for use and that their labeling, marketing and promotional materials fully described all known risks associated with their product.
- Manufacturing Defendants' representations were in fact false. Gadolinium-based contrast agents are not safe for use and Defendants' labeling, marketing and promotional materials did not fully describe all known risks of the products.
- Manufacturing Defendants had actual knowledge that gadolinium-based contrast agents created an unreasonable risk of serious bodily injury and death to consumers, especially patients with renal impairment.
- Manufacturing Defendants knowingly and intentionally omitted this information from their 78. labeling, marketing, and promotional materials and instead, labeled, promoted and marketed their products as safe for use in order to increase and sustain sales.
- When Manufacturing Defendants made representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Mrs. Moorhouse, her healthcare providers and the public, the fact that their gadolinium-based contrast agents are not safe for use in consumers with renal insufficiency.
- Manufacturing Defendants had a duty to disclose that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency. Manufacturing Defendants had superior knowledge of these facts that were material to Mrs. Moorhouse and her healthcare providers' decisions to use gadolinium-based contrast agents.
- Mrs. Moorhouse and her healthcare providers reasonably and justifiably relied on the Manufacturing Defendants' representations that gadolinium-based contrast agents were safe for human use and that Manufacturing Defendants' labeling, marketing and promotional materials fully described all

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- 82. Mrs. Moorhouse did not know, and could not have learned of the facts that the Defendents omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Mrs. Moorhouse and her healthcare providers known that gadolinium-based contrast agents are not safe for use in patients with renal insufficiency, Mrs. Moorhouse would not have been injected with gadolinium-based contrast agents.
- 83. As a direct and proximate result of Manufacturing Defendants' misrepresentations and concealment, Mrs. Moorhouse was administered gadolinium-based contrast agents and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 84. The foregoing acts, conduct and omissions of Manufacturing Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Mrs. Moorhouse and other users of Manufacturing Defendants' products, and for the primary purpose of increasing Manufacturing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

#### FOURTH CAUSE OF ACTION

(Against Manufacturing Defendants)

### FRAUD: CONCEALMENT, SUPPRESSION OR

#### OMISSION OF MATERIAL FACTS

- 85. Plaintiffs incorporate by reference and reallege each paragraph set forth above.
- 86. Manufacturing Defendants omitted, suppressed, or concealed material facts concerning the dangers and risk associated with the use of their gadolinium-based contrast agents, including but not limited to the risks to patients with kidney impairment of developing NSF, and the fact that safer alternatives were available. Further, Manufacturing Defendants purposely downplayed and understated the serious nature of the risks associated with use of their gadolinium-based contrast agents in order to increase and sustain sales.
  - 87. As a direct and proximate result of Manufacturing Defendants' concealment of material

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27 28 facts, Mrs. Moorhouse was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

88. The foregoing acts, conduct and omissions of Manufacturing Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Mrs. Moorhouse and other users of Manufacturing Defendants' products, and for the primary purpose of increasing Manufacturing Defendants' profits. As such Plaintiffs are entitled to exemplary damages.

### FIFTH CAUSE OF ACTION

(Against Manufacturing Defendants)

### NEGLIGENT MISREPRESENTATION

- 89. Plaintiffs incorporate by reference and reallege each paragraph set forth above.
- 90. Manufacturing Defendants supplied the public and Mrs. Moorhouse's healthcare providers with materially false and incomplete information with respect to the safety of their gadolinium-based contrast agents.
- 91. The false information supplied by Manufacturing Defendants was that gadolinium-based contrast agents were safe.
- 92. In supplying this false information, Manufacturing Defendants failed to exercise reasonable care.
- 93. The false information communicated by Defendants to Mrs. Moorhouse and her healthcare providers was material and Mrs. Moorhouse justifiably relied in good faith on the information to her detriment.
- 94. As a direct and proximate result of Defendants' misrepresentations, Mrs. Moorhouse was administered gadolinium-based contrast agents and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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#### SIXTH CAUSE OF ACTION

Document 1-2

#### (Against All Defendants)

#### CONSUMER LEGAL REMEDIES ACT

- Plaintiffs incorporate by reference and reallege each paragraph set forth above. 95.
- This Complaint is filed and these proceedings are instituted, pursuant to California Civil 96. Code section 1750, et seq, commonly referred to as the Consumers Legal Remedies Act ("CLRA"), to obtain injunctive relief, restitution, any other relief this Court deems proper, and attorneys' fees from Defendants.
- Among others, Defendants' conduct is in violation of California Civil Code section 97. 1770(5), 1770(7) and 1770(9). Defendants' acts and business practices constitute unlawful methods of competition and unfair or deceptive acts within the meaning of California Civil Code section 1750, et seq, including but not limited to the following:
  - a. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance for use with MRAs and other off-label uses by impliedly representing that such products are approved for use with MRAs and other off-label uses, when in fact there is no such approval;
  - b. Representing that gadolinium-based contrast agents are safe and effective for all patients, including patients with kidney impairment, when in fact they are not;
  - c. Representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents when in fact they are not;
  - d. Marketing, promoting or selling their products as safer or superior to other brands of gadolinium-based contrast agents;
  - e. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance as inert or with words to that effect;
  - f. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance for use with MRAs or other off-label uses by expressly or impliedly representing that they are safe for such use; and

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- Remaining silent despite their knowledge of the growing body of evidence regarding the danger of NSF and doing so because the prospect of huge profits outweighed health and safety issues.
- 98. Plaintiffs demand that Defendants immediately cease the illegal conduct alleged herein.
- 99. The illegal conduct alleged herein is continuing and there is no indication that Defendants will refrain from such activity in the future.
- 100. Plaintiffs are entitled to injunctive relief and any other relief this Court deems proper, and attorneys' fees from Defendants as a result of such acts or practices.

#### SEVENTH CAUSE OF ACTION

(Against all Defendants)

#### LOSS OF CONSORTIUM

- 101. James Moorhouse incorporates by reference and realleges each paragraph set forth above.
- 102. Mr. Moorhouse is the husband of Mrs. Moorhouse.
- 103. As a direct and proximate result of Defendants' conduct, Mr. Moorhouse has been deprived of his wife's love, society, companionship and services and has otherwise suffered loss, the extent of which will be more fully adduced at the trial of this matter.

WHEREFORE, Plaintiffs pray for relief as follows:

- 1. For an injunction prohibiting Defendants from engaging in the following conduct which violates the CLRA:
  - Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance for use with MRAs and other off-label uses;
  - Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance as safe and effective for patients with kidney impairment;
  - ProHance as by representing that MRIs and MRAs using gadolinium-based contrast agents are safer or more effective than other imaging methods that do not require the use of gadolinium-based contrast agents;

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- d. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance in any way which implies that those products are safer or superior to other brands of gadolinium-based contrast agents;
- e. Marketing, promoting or selling Magnevist, Omniscan, OptiMark, MultiHance or ProHance as inert or with words to that effect.
- 2. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, and other non-economic damages in an amount to be determined at trial of this action;
- Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
  - 4. Punitive damages in an amount to be determined at trial of this action;
  - 5. Pre- and post-judgment interest;
  - 6. Attomeys' fees, expenses, and costs; and
  - Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted this 4th day of March 2008.

LEVIN SIMES KAISER & GORNICK LLP

CT CORPORATION

A WoltersKluwer Company

Service of Process **Transmittal** 

03/07/2008

CT Log Number 513168602

TO: Deb Missell

GE Healthcare Inc. 101 Camegie Center Princeton, NJ 08540-6231

RE: **Process Served in California** 

FOR: GE Healthcare Inc. (Domestic State, DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION: Carol Moorhouse and James Moorhouse, Pltfs. vs. Bayer Healthcare Pharmaceuticals, Inc., etc., et al. including GE Healthcare, Inc., Dfts.

DOCUMENT(S) SERVED: Summons, Cover Sheet, Affidavit, Complaint, Stipulation Form, Case Management

Statement Form, Attachment(s)

COURT/AGENCY: San Francisco County- San Francisco, Superior Court, CA Case # CGC08472978

NATURE OF ACTION: Product Liability Litigation - Drug Litigation - Magnevist - A gadolinium based agent

ON WHOM PROCESS WAS SERVED: C.T. Corporation System, Los Angeles, CA

DATE AND HOUR OF SERVICE: By Process Server on 03/06/2008 at 14:45

APPEARANCE OR ANSWER DUE: Within 30 days after service

ATTORNEY(S) / SENDER(S): awrence J. Gornick

Levin Simes Kaiser & Gornick LLP 44 Montgomery Street

Suite 3600 San Francisco, CA 94104

ACTION ITEMS: SOP Papers with Transmittal, via Fed Ex Standard Overnight, 798391487840

SIGNED: C T Corporation System PER: Nancy Flores 818 West Seventh Street ADDRESS:

Los Angeles, CA 90017 213-337-4615 TELEPHONE:

Page 1 of 1 / WM

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Defendant McKESSON CORPORATION ("McKesson") answers Plaintiffs' Complaint as follows:

Under the provisions of Code of Civil Procedure Section 431.30, McKesson denies each and every allegation of said Complaint and denies that Plaintiffs sustained damages in the sum or sums alleged, or in any other sum, or at all.

Further answering, and by way of additional defense, McKesson states as follows:

#### DEFENSES

- 1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.
- 2. Plaintiffs' claims are barred in whole or in part by the applicable statutes of limitations, statutes of repose, and/or by the doctrines of laches, estoppel, waiver, unclean hands, or ratification.
- 3. Adequate warnings were provided to Carol Moorhouse's physicians and other medical providers; therefore, any claims by Plaintiffs for inadequate warnings are barred by the doctrines of learned intermediary and/or sophisticated user.
- 4. Plaintiffs' claims based on inadequate warning are barred even if adequate warnings with respect to known or potential dangers or risks associated with the use of Omniscan<sup>TM</sup> were not provided, which is denied, because physicians and other medical providers prescribing Omniscan<sup>TM</sup> either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or which should be known to members of the profession.
- 5. Plaintiffs' claims are barred in whole or in part because the products, methods, standards, and/or techniques used in manufacturing, designing, marketing, and/or labeling of the products at issue complied with and/or were in conformity with the state of the art at the time they were manufactured, designed, marketed, and/or labeled.
- 6. Plaintiffs' claims are barred in whole or in part because the manufacture, labeling and sale of Omniscan<sup>™</sup> was and is controlled by federal law, and McKesson at all relevant times complied with applicable statutes and with the requirements of the FDA.

-2-

- 7. Plaintiffs' claims are barred in whole or in part to the extent Plaintiffs have released, settled, entered into an accord and satisfaction, or otherwise compromised their claims.
- 8. Plaintiffs' claims are barred in whole or in part by Carol Moorhouse's assumption of the risk associated with the purchase and/or use of the product, and is imputed to plaintiff James Moorhouse.
- 9. Plaintiffs' claims are barred in whole or in part by product misuse by Plaintiff Carol Moorhouse or her physician including, among other things, their failure to follow warnings and/or failure to follow instructions.
  - 10. Plaintiffs' claims under state law are barred by the doctrine of federal preemption.
- 11. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the FDA over the subject pharmaceutical product at issue under applicable federal laws, rules, and regulations.
- 12. Plaintiffs' claims are barred in whole or in part under the doctrine described in the Restatement (Second) of Torts § 402A cmt.k.
- 13. Plaintiffs' claims are barred in whole or in part because the pharmaceutical product at issue provides net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt.f.
- 14. To the extent Plaintiffs' claims related to McKesson's advertising, marketing, public statements, lobbying or other activities are protected by the First Amendment to the United States Constitution and the California Constitution, such claims are barred.
- 15. Plaintiffs failed to notify McKesson of any alleged breach of warranty within a reasonable time after they discovered or should have discovered any such alleged breach and are therefore barred from recovery on such claims.
  - 16. Any warranties made by McKesson to Plaintiffs were disclaimed.
- 17. Any claim for breach of express warranty must fail because Plaintiffs failed to allege any representation about the product at issue giving rise to an express warranty.
- 18. Any claim for breach of implied warranty fails because the product at issue was used for its ordinary purpose.

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19.	Any	breach	of	warranty	claims	are	barred	because	there	is	a	lack	of	privity
between Plain	tiffs a	nd McK	ess	on.										

- McKesson specifically pleads all defenses under the Uniform Commercial Code 20. now existing or which may arise in the future.
- Plaintiffs' claims for breach of warranty, expressed or implied, are barred by the 21. applicable provisions of the California Commercial Code.
- Plaintiffs have failed to join all indispensable parties; as a result of this failure, 22. complete relief cannot be accorded to those already parties to this action and will result in prejudice to McKesson
- Plaintiffs' claims and recovery are barred, reduced and/or limited pursuant to 23. applicable constitutional, statutory, and common law regarding limitations of awards and recovery.
- Plaintiffs' claims are barred or reduced by the contributory and/or comparative 24. negligence, and/or contributory and/or comparative fault.
- Plaintiffs' damages, if any, were caused solely or partially by some third person or third party for whom McKesson is not legally responsible.
- Plaintiffs' damages, if any, resulted from new and independent, unforeseeable, superseding, or intervening causes unrelated to the conduct of McKesson, or the products at issue.
- 27. If McKesson provided any product alleged to have been defective, as alleged in the Complaint, McKesson supplied and/or distributed such product by and through other intermediaries, including plaintiffs' and/or other named and unnamed defendants, and did not package, repackage, or label the product in any way, and provided all warnings regarding the product to such intermediaries as they were received from the product manufacturer and/or other up stream suppliers without any additions, deletions, or alterations of any kind to the warnings.
- Plaintiffs' damages, if any, were the result of pre-existing conditions unrelated to any conduct of McKesson or the products at issue.

- Plaintiffs' damages, if any, were caused by changes and/or alterations to the 29. products at issue and were made by persons not within McKesson's control.
- McKesson's liability, if any, for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to Plaintiffs' total non-economic loss, if any, including those over whom Plaintiffs could have obtained personal jurisdiction with due diligence.
- McKesson alleges that the provisions of California Civil Code § 1431.2 are 31. applicable to the Complaint and each cause of action therein.
- Plaintiffs' non-economic loss must be allocated in accordance with the provisions 32. of Cal. Civil Code § 1431.2 ("Proposition 51").
- Plaintiffs' damages, if any, must be reduced by any amount of damages legally 33. caused by Plaintiffs' own failure to mitigate such damages.
- Plaintiffs' damages, if any, are not recoverable because they are legally too remote, indirect, and speculative.
- Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.
- McKesson denies any conduct for which punitive or exemplary damages could or 36. should be awarded and denies that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.
- Plaintiffs' claims seeking punitive damages violate the substantive and procedural aspects of the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, the Equal Protection Clause, the Excessive Fines Clause, and the cognate provisions of the California Constitution.
- Any award of punitive or exemplary damages is barred to the extent that it is 38. inconsistent with the standards and limitations set forth in BMW of North American, Inc. v. Gore, 517 U.S. 559, 134 L.Ed. 2d 809, 116 S.Ct. 1589 (1996); State Farm Mutual Automobile Insurance Co. v. Campbell, 538 U.S. 408 (2003), and Phillip Morris USA v. Williams, 127 S.Ct. 1057 (2007).

39. No act or alleged omission of McKesson was vile, base, willful, malicious,
wanton, oppressive or fraudulent, or done with a conscious disregard for the health, safety and
rights of Plaintiffs and others, or with actual malice, fraud or oppression as defined in Cal. Civil
Code § 3294, and Plaintiffs' Complaint fails to state a claim upon which relief can be granted for
punitive or exemplary damages. Plaintiffs' Complaint seeks damages in excess of those
permitted by law. McKesson asserts any statutory or judicial protection from punitive or
exemplary damages that is available under the applicable law, and any award of punitive or
exemplary damages is barred.

- 40. Any verdict or judgment that might be recovered by Plaintiffs must be reduced by those amounts that have indemnified, or will in the future indemnify, Plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, Social Security, workers' compensation, or employee benefit programs.
- Plaintiffs' claims are barred by applicable statutes of limitation, including but not limited to Cal. Code of Civil Procedure former § 340, subd. 3, or in the alternative, Cal. Code of Civil Procedure §§ 335.1, 340.5, 340.8 and/or 343.
- 42. McKesson is not liable to Plaintiffs because it never manufactured, sold, or administered any gadolinium-based contrast agent to the Plaintiffs.
- McKesson owed no duty to Plaintiffs, and in any event, violated no duty that it 43. may have owed to Plaintiffs.
- 44. Any and all injuries suffered by Plaintiffs, the fact of which is expressly denied by McKesson, were in direct and proximate result of sensitivities, medical conditions, reactions and/or idiosyncrasies peculiar to Plaintiff Carol Moorhouse that were unknown, unknowable, or not reasonably foreseeable to McKesson, and not as a direct and proximate result of wrongful convictions on the part of the McKesson, the fact of which is expressly denied by McKesson.
- No act or omission of McKesson was a substantial factor in bringing about the alleged injuries of Plaintiffs, nor was any such act or omission a contributing cause thereof, and any alleged acts or omissions of McKesson were superseded by the acts or omissions of others, including Plaintiffs, which were the independent, intervening and proximate cause of any injury,

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damage or loss sustained by Plaintiffs.

- Plaintiffs' cause of action for alleged violation of the California Consumer Legal Remedies Act ("CLRA"), Cal Civil Code § 1750, et seq., is barred because Plaintiffs failed to give proper notice as mandated by Cal. Civil Code § 1782(a)(1). Since strict compliance with the notice provisions of the CLRA is required, Plaintiffs' CLRA cause of action must be dismissed with prejudice.
- Plaintiffs' cause of action for alleged violation of the California Consumer Legal 47. Remedies Act ("CLRA"), Cal Civil Code § 1750, et seq., is barred because Plaintiffs failed to comply with the affidavit requirement of Cal. Civil Code § 1780(c). Since strict compliance with the notice provisions of the CLRA is required, Plaintiffs' CLRA cause of action must be dismissed with prejudice.
- Plaintiffs' Complaint fails to state a claim under the California Consumer Legal 48. Remedies Act ("CLRA"), Cal Civil Code § 1750, et seq., because the CLRA is inapplicable to a pharmaceutical products liability action.
- 49. Plaintiffs' claims are barred in whole or in part because Plaintiffs consented to the alleged wrongful conduct.

McKesson adopts and incorporates by reference each and every other or additional defense that is or may be applicable to McKesson that has been or may be pleaded by any other defendants to this action not otherwise set forth herein.

WHEREFORE, McKesson prays that Plaintiffs take nothing by reason of said Complaint; that McKesson be awarded costs of suit herein, including reasonable attorneys fees where authorized by statute, contract or law, and such other and further relief as the court deems just; and, that if McKesson is found liable, the degree of its responsibility for the resulting damages be determined and that McKesson be held liable only for that amount of the total damages proportionate to its responsibility for the same.

ANSWER OF MCKESSON CORPORATION AND DEMAND FOR JURY TRIAL

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]	Charles of the Control of the Contro	DEMAND FOR JURY TRIAL
2	McKesson hereby den	nands a trial by jury of the above-captioned matter.
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4	DATED: April 3, 2008	Respectfully submitted,
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6		SEDGWICK, DETERT, MORAN & ARNOLD LLP
7		
8		By: Charles T. Charles
9		Charles T. Sheldon Michael L. Fox Marc Brainich
10		and
11		
12	,	Galen D. Bellamy Wheeler Trigg Kennedy LLP
13		Attorneys for Defendant McKesson Corporation
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#### PROOF OF SERVICE

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. My business address is Sedgwick, Detert, Moran & Arnold LLP, One Market Plaza, Steuart Tower, 8th Floor, San Francisco, California 94105. On April 3, 2008, I served the within document(s):

#### ANSWER OF MCKESSON CORPORATION AND DEMAND FOR JURY TRIAL

- FACSIMILE by transmitting via facsimile the document(s) listed above to the fax number(s) set forth on the attached Telecommunications Cover Page(s) on this date.
- MAIL by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at San Francisco, California addressed as set forth below.
- ☐ PERSONAL SERVICE by personally delivering the document(s) listed above to the person(s) at the address(es) set forth below.
- OVERNIGHT COURIER by placing the document(s) listed above in a sealed envelope with shipping prepaid, and depositing in a collection box for next day delivery to the person(s) at the address(es) set forth below via

#### SEE ATTACHED SERVICE LIST

I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Executed on April 3, 2008, at San Francisco, California.

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ANSWER OF MCKESSON CORPORATION AND DEMAND FOR JURY TRIAL

20:24 APR-03-2008 Frank C. Rothrock (SBN: 54452) Thomas A. Woods (SBN: 210050) AF# 03 2008 SHOOK HARDY & BACON LLP. Jaroboree Center 3 5 Park Place, Suite 16th WEDLEYSAMPREZ Irvine, California 92614-2546 Deputy Dlenk 4 Telephone (949) 475-1500 Facsimile: (949) 475-0016 5 Attorneys for Defendants denominated "Covidien, Inc." б and "Mallinckrodi, Inc." 7 8 SUPERIOR COURT FOR THE STATE OF CALIFORNIA 9 FILED BY FAX COUNTY OF SAN FRANCISCO 10 CAROL MOORHOUSE and JAMES CASE NO.: CGC-08-472978 MOORHOUSE, 14 Plaintiffs. ANSWER AND AFFIRMATIVE 12 DEFENSES OF DEFENDENTS DENOMINATED COMPERN, INC." AND 13 MALLINCKRODT BEE BAYER HEALTHCARE 14 PHARMACEUTICALS, INC., BAYER HEALTHCARE LLC; GENERAL ELECTRIC COMPANY; GE HEALTHCARE, INC.; Complaint Pilet: Mar. 5, 2008 Case Management Cont. Aug. 8, 2008 COVIDIEN, INC.: MALLINCKRODT, INC.: BRACCO DIAGNOSTICS, INC.; MCKESSON CORPORATION; MERRY X-RAY CHEMICAL CORP.; and DOES 1 17 through 35 18 Defendants. 19 20 21 Defendants denominated "Covidien, Inc." and "Mallinckrodt, Inc." ("Defendants") answer Plaintiffs' Complaint as follows: 22 23 GENERAL DENIAL 24 Pursuant to Code of Civil Procedure section 43130 subdivision (d). 25

Defendants generally and specifically deny each and every allegation in Plantiffs' Complaint, the whole thereof, and each and every cause of action therein, and further depy that Plaintiffs have sustained or are entitled to recover damages in the sum alleged, or in any sum whatsoever. Further, answering Plaintiff's Complaint, Defendants deny Plaintiffs have sustained any injury, damage, or ANSWER AND APPENDATIVE DEFENSES

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loss by reason of any act or omission by these answering Defendants.

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AFFIRMATIVE DEFENSES

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AFFIRMATIVE DEFENSES

1. Defendants set forth below their affirmative defenses. By setting forth these affirmative defenses, Defendants do not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiffs. Moreover, nothing herein stated is intended or shall be construed as an acknowledgment that any particular issue or subject matter is relevant to Plaintiffs' allegations.

# FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

2. Plaintiffs' Complaint, including each and every count thereof, fails to state a claim upon which relief can be granted against Defendants.

# SECOND AFFIRMATIVE DEFENSE

(Preemption - Supremacy Clause)

3. Pursuant to the Supremacy Clause of the United States Constitution, the claims set forth in the Complaint are preempted by the Food, Drug and Cosmetic Act (F.D.C.A.), 21 U.S.C. § 301 et seq. and any ensuing regulations promulgated by the Food and Drug Administration contained in Chapter 21 of the Code of Federal Regulations. The product referred to in the Complaint was and is controlled by federal law, which governs the manufacture, distribution, and sale of said products at all times. Plaintiffs' claims are thus preempted in whole or in part such that they fail to state a cause of action upon which relief can be granted.

Exh. A -45-

# THIRD AFFIRMATIVE DEFENSE

# (Superseding/Intervening Cause)

4. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by one or more unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

### FOURTH AFFIRMATIVE DEFENSE

# (Causation – Preexisting Condition)

5. If Plaintiffs have been damaged, which Defendants deny, those damages, if any, were caused by medical conditions or processes (whether pre-existing or contemporaneous) unrelated to OptiMARK®.

# FIFTH AFFIRMATIVE DEFENSE

### (Learned Intermediary Doctrine)

6. Plaintiffs' claims are barred by the learned intermediary doctrine.

### SIXTH AFFIRMATIVE DEFENSE

#### (Brown v. Superior Court/Restatement (Second) & (Third) of Torts)

7. Plaintiffs' claims are barred, in whole or in part, by the limitations upon the doctrine of strict product liability as set forth in *Brown v. Superior Court* (1988) 44 Cal.3d 1049, Comment (j) and/or Comment (k) of § 402A of the Restatement (Second) of Torts, as well as by §§ 4 and 6 of the Restatement (Third) of Torts (Product Liability).

# SEVENTH AFFIRMATIVE DEFENSE

# (State-of-the-Art)

8. The claims set forth in the Complaint are barred because the methods, standards and techniques used in formulating OptiMARK® and in issuing warnings and instructions about its use conformed to the generally recognized, reasonably available and reliable state of knowledge in the field at the time OptiMARK® was manufactured. All acts of Defendants at the time of the alleged manufacture, sale and/or distribution of the product at issue were in conformity with the state-of-theart at such times. Further, the methods, standards, and techniques used in manufacturing and/or

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marketing the product at issue, and in issuing warnings and instructions with respect to the use of such product, were in conformity with industry custom, usage, and standards and/or legislative, administrative, and regulatory standards. Any alleged defects of the product at issue, and/or any alternative design claimed by Plaintiffs were not known and, in light of the existing, reasonably available scientific and technological knowledge, could not have been known. Any such alternative design was not scientifically or technologically feasible, nor was it economically practical.

# EIGHTH AFFIRMATIVE DEFENSE

(Informed Consent/Assumption of Risk)

9. The claims set forth in Plaintiffs' Complaint are barred by the doctrines of informed consent and assumption of risk.

# **NINTH AFFIRMATIVE DEFENSE**

# (Scientifically Unknown/Unknowable Risk)

10. The design characteristics complained of in Plaintiffs' Complaint, the alleged defects of the product at issue, and/or any alternative design claimed by Plaintiffs were not known and, in light of the existing, reasonably available scientific and technological knowledge, could not have been known. Any such alternative design was not scientifically or technologically feasible, nor was it economically practical.

# TENTH AFFIRMATIVE DEFENSE

#### (Lack of Defect)

11. At no time was OptiMARK® defective or unreasonably dangerous.

# ELEVENTH AFFIRMATIVE DEFENSE

# (Causation – Lack of Proximate Cause/Substantial Factor)

12. Any conduct by Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of the injuries alleged in the Complaint.

Exh. A -47-

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# TWELFTH AFFIRMATIVE DEFENSE

# (Defense of Consent)

13. Plaintiffs' claims are barred because Plaintiffs were aware of the known risks associated with the use of OptiMARK®.

# THIRTEENTH AFFIRMATIVE DEFENSE

### (Federal Preemption)

14. Plaintiffs' claims are barred because Defendants complied with all applicable statutes and with the requirements and regulations of the FDA.

# FOURTEENTH AFFIRMATIVE DEFENSE

### (Product Misuse/Alteration)

15. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by any misuse and/or abuse of the product at issue. The product described in Plaintiffs' Complaint vas modified, altered, or changed from the condition in which it was sold, and this modification, Iteration, or change caused plaintiffs' alleged damages, if any.

#### FIFTEENTH AFFIRMATIVE DEFENSE

# (Failure to State a Claim - Uncertainty - Lack of Specificity)

16. Plaintiffs' fraud-based claims (including misrepresentation) are barred by the failure plead the necessary elements of those claims with particularity.

# SIXTEENTH AFFIRMATIVE DEFENSE

# (Lack of Reliance)

17. Defendants deny that Plaintiffs reasonably or justifiably relied on any alleged epresentation or other conduct by any of the answering Defendants to their detriment.

# SEVENTEENTH AFFIRMATIVE DEFENSE

# (Contributory Fault/Negligence - Plaintiff)

18. If Plaintiffs have been damaged, which Defendants deny, such damages were caused in whole or in part by the negligence/fault of Plaintiffs.

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Exh. A -48-

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# EIGHTEENTH AFFIRMATIVE DEFENSE

# (Contributory Fault/Negligence - Others)

19. If Plaintiffs have been damaged, which Defendants deny, such damages were caused in whole or in part by the negligence/fault of one or more persons and/or entities for whose conduct Defendants are not legally responsible. Such contributory negligence bars, in whole or in part, the damages, if any, that Plaintiffs seeks to recover herein.

# NINETEENTH AFFIRMATIVE DEFENSE

# (Federal Preemption)

20. Plaintiffs' claims against Defendants are expressly and/or impliedly preempted by federal law, including, but not limited to, the provisions of the Public Health Service Act, 42 U.S.C. § 301, et seq., and any ensuing regulations promulgated by the Food and Drug Administration contained in Chapter 21 of the Code of Federal Regulations.

# TWENTIETH AFFIRMATIVE DEFENSE

# (Proposition 51)

21. The liability of these answering Defendants, if any, in this action is subject to the limitations set forth in the Fair Responsibility Act of 1986 (Civ. Code, §§ 1431-1431.5).

# TWENTY-FIRST AFFIRMATIVE DEFENSE

#### (Constitutional Defenses – Joint & Several Liability)

- 22. If Plaintiffs sustained damages, which Defendants deny, the application of joint and several liability law violates Defendants' Constitutional rights under the Fifth, Sixth, Eighth and Fourteenth Amendments of the United States Constitution and the California Constitution, in one or more of the following respects:
- (a) The application of joint and several liability is equivalent to the imposition of an excessive fine or cruel and unusual punishment;
- (b) The application of joint and several liability exposes Defendants to multiple punishments and fines for the same act;

Exh. A -49-

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1	TWENTY-FIFTH AFFIRMATIVE DEFENSE
2	(Equitable Defenses/Laches/Estoppel)
3	26. Each purported cause of action of Plaintiffs' Complaint is barred by the equitable
4	doctrines of laches, waiver, good faith, and estoppel.
5	TWENTY-SIXTH AFFIRMATIVE DEFENSE
6	(Failure to Join Indispensable Parties)
7	27. Plaintiffs' claims are barred for failure to join indispensable parties.
8	TWENTY-SEVENTH AFFIRMATIVE DEFENSE
9	(Improper Joinder)
10	28. Plaintiffs' Complaint is an improper joinder and an improper accumulation of parties.
11	TWENTY-EIGHTH AFFIRMATIVE DEFENSE
12	(Failure to State a Claim – Punitive Damages)
13	29. Plaintiffs have failed to state a claim for which punitive damages may be awarded.
14	TWENTY-NINTH AFFIRMATIVE DEFENSE
15	(Failure to State a Claim/Failure of Proof – Punitive Damages)
16	30. Plaintiffs' claim for punitive damages fails to allege facts which meet the clear and
17	convincing standards of proof required for an award of punitive damages.
18	THIRTIETH AFFIRMATIVE DEFENSE
19	(Constitutional Defenses – Punitive Damages)
20	31. Insofar as Plaintiffs seek recovery of punitive damages, their claims are barred by the
21	provision of the Fifth, Eighth, and Fourteenth Amendments of the United States Constitution and
22	article 1, sections 7, 15, 16, and 17 of the California Constitution for each of the following reasons:
23	(a) California law fails to provide adequate notice of the conduct that will subject a
24	defendant to punitive damages;
25	(b) California law fails to provide a defendants with adequate notice of the severity of the
26	penalty that may be imposed in the form of punitive damages;
27	
28	Exh. A -51-

- (c) California law permits the imposition of grossly excessive penalties in the form of punitive damages;
- (d) California law fails to provide a meaningful and appropriate review of punitive damage awards by trial and appellate courts and fails to provide for de novo review of such awards as mandated in Cooper Industries, Inc. v. Leatherman Tool Group, Inc. (2001) 532 U.S. 424;
- Notwithstanding the fact that punitive damages are quasi-criminal in nature, California law fails to require proof beyond a reasonable doubt and a verdict by a unanimous jury as a condition to the imposition of punitive damages;
- (f) California law permits the assessment and measure of punitive damages to be based, in significant part, upon the wealth of the defendant; and
- (g) Plaintiffs' claim for punitive damages cannot be sustained to the extent it seeks to punish defendants for alleged harm to non-parties or persons who are not before the court because imposition of punitive damages under such circumstances would violate Defendants' procedural and substantive due process rights and equal protection rights under the Fifth and Fourteenth Amendments to the United States Constitution and defendants' due process and equal protection rights under article 1, section 7 of the California Constitution, and would be improper under the common law and public policies of the United States and California.

# THIRTY-FIRST AFFIRMATIVE DEFENSE

(Offset)

32. Defendants are entitled to a set-off, should any damages be awarded against it, for the entire amount of damages or settlement amounts recovered from other sources.

# THIRTY-SECOND AFFIRMATIVE DEFENSE

(Offset)

33. Defendants are entitled to an offset of any prejudgment monies received by Plaintiffs from any settling defendant pursuant to Code of Civil Procedure Section 877, subdivision (a).

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### THIRTY-THIRD AFFIRMATIVE DEFENSE 1 2 (Offset) 3 34. Should defendants be held liable to Plaintiffs, which liability is specifically denied, 4 Defendants would be entitled to a set off for the total of all amounts paid to Plaintiffs from all 5 collateral sources. THIRTY-FOURTH AFFIRMATIVE DEFENSE 6 7 (Failure of Notice - CLRA) 8 35. Plaintiffs' cause of action for alleged violation of the California Consumer Legal 9 Remedies Act ("CLRA") is barred by Plaintiffs' failure to provide proper notice as required by Cal. 10 Civ. Code § 1782 (a)(1). 11 THIRTY-FIFTH AFFIRMATIVE DEFENSE 12 (Failure of Affidavit Requirement – CLRA) 13 36. Plaintiffs' cause of action for alleged violation of the California Consumer Legal 14 Remedies Act ("CLRA") is barred because Plaintiffs failed to comply with the affidavit requirement 15 of Cal. Civ. Code § 1780(c). 16 THIRTY-SIXTH AFFIRMATIVE DEFENSE 17 (Failure to State a Claim) 18 37. Plaintiffs' cause of action for alleged violation of the California Consumer Legal 19 Remedies Act ("CLRA") fails to state a claim against Defendants to the extent the CLRA is inapplicable to pharmaceutical products liability actions. 20 21 THIRTY-SEVENTH AFFIRMATIVE DEFENSE 22 (Unintentional Acts/Bona Fide Error Defense) 23 38. Plaintiffs' cause of action for alleged violation of the California Consumer Legal Remedies Act ("CLRA"), if any, is precluded by the defenses available under Civ. Code § 1784. 24 25 /// /// 26 27 /// Exh. A

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-53-

# THIRTY-EIGHTH AFFIRMATIVE DEFENSE

# (Violation of Commerce Clause)

39. Plaintiffs' claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution because they purport to regulate interstate commerce and impermissibly place an undue burden on interstate commerce.

Dated: April 3, 2008

SHOOK, HARDY & BACON L.L.P.

Frank C. Rothrock
Thomas A. Woods

Attorneys for Defendants denominated "Covidien, Inc." and "Mallinckrodt, Inc."

Exh. A -54-

### PROOF OF SERVICE 1 I am employed in the County of Orange, State of California. I am over the age of 18 2 and not a party to the within action. My business address is 5 Park Plaza, Suite 1600, Irvine, California 92614. 3 4 On April 3, 2008 I served on the interested parties in said action the within: 5 ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS DENOMINIATED "COVIDIEN, INC." AND "MALLINCKRODT, INC." 6 by placing a true copy thereof in a sealed envelope(s) addressed as stated on the attached mailing list. 8 $\boxtimes$ (MAIL) I am readily familiar with this firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal 9 service on that same day in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more 10 than 1 day after date of deposit for mailing in affidavit. 11 (FAX) I caused such document(s) to be served via facsimile on the interested parties at their facsimile numbers listed above. The facsimile numbers used complied with California Rules of 12 Court, Rule 2003, and no error was reported by the machine. Pursuant to California Rules of Court, Rule 2006(d), I caused the machine to print a report of the transmission, a copy of which 13 is attached to the original of this declaration. 14 (HAND DELIVERY) By placing a true and correct copy of the above document(s) in a sealed envelope addressed as indicated above and causing such envelope(s) to be delivered by hand to 15 the addressee(s) designated. 16 (BY FEDERAL EXPRESS, AN OVERNIGHT DELIVERY SERVICE) By placing a true and correct copy of the above document(s) in a sealed envelope addressed as indicated above and 17 causing such envelope(s) to be delivered to the FEDERAL EXPRESS Service Center, on December 9, 2004, to be delivered by their next business day delivery service on November 10, 18 2004, to the addressee designated. 19 (State) I declare under penalty of perjury under the laws of the State of California that 20 the foregoing is true and correct. 21 Executed on April 3, 2008, at Irvine, California. 22 23 Kim Brunton (Type or print name) 24 25 26 27 28

Exh. A -55-

*	
1	<u>SERVICE LIST</u>
2	
3	Debra DeCarli, Esq. Lawrence J. Gornick, Esq.
4	LEVIN SIMES KAISER & GORNICK LLP
5	44 Montgomery Street, Suite 3600 San Francisco, CA 94104
6 7	Tel: (415) 646-7160
8	Fax: (415) 981-1270 Attorneys for Plaintiffs CAROL
8 9	MOORHOUSE and JAMES MOORHOUSE
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# **EXHIBIT "B"**

1 RODNEY M. HUDSON (State Bar No. 189363) DRINKER BIDDLE & REATH LLP 2 50 Fremont Street, 20th Floor San Francisco, California 94105-2235 Telephone: (415) 591-7500 Facsimile: (415) 591-7510 3 4 Attorneys for Defendants 5 BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER HEALTHCARE LLC 6 7 8 SUPERIOR COURT OF THE STATE OF CALIFORNIA 9 FOR THE COUNTY OF SAN FRANCISCO 10 11 CAROL MOORHOUSE and JAMES Case No. CGC-08-472970 MOORHOUSE, 12 **DEFENDANTS BAYER** Plaintiffs, HEALTHCARE 13 PHARMACEUTICALS, INC. AND BAYER HEALTHCARÉ, LLC'S 14 CONSENT TO REMOVAL OF BAYER HEALTHCARE ACTION 15 PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC: GENERAL 16 ELECTRIC COMPANY: GE HEALTHCARE, INC.; COVIDIEN, INC.; MALLINCKRODT, INC.; BRACCO 17 DIAGNOSTICS, INC.; McKESSON CORPORATION; MERRY X-RAY 18 CHEMICAL CORP.; and DOES 1 through 19 20 Defendants. 21 22 Defendants BAYER HEALTHCARE PHARMACEUTICALS, INC. ("BHCP") 23

and BAYER HEALTHCARE LLC ("BHC") hereby consent to the removal of this action by co-defendants GENERAL ELECTRIC COMPANY and GE HEALTHCARE, INC.

BHCP and BHC were served with the original complaint in this action on March 6, 2008. For purposes of diversity jurisdiction, BHCP is a Delaware corporation with its principal place of business in New Jersey. BHC is a Delaware limited liability company whose sole member is Bayer Corporation. For purposes of BHC's citizenship

DRINKER BIDOLE & REATH UP 50 Fremont Street, 20th Floor San Francisco, CA 94105

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as a limited liability company, Bayer Corporation is incorporated under the laws of Indiana with its principal place of business in Pennsylvania.

Dated: April 2, 2008

DRINKER BIDDLE & REATH LLP

Attorneys for Defendants BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER HEALTHCARE LLC

DRINKER BIDDLE & REATH ELP 50 Fremont Street, 20th Floor San Francisco, CA 94105

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CONSENT TO REMOVAL OF ACTION

**EXHIBIT "C"** 

	1	
1 2 3 4 5 6 7 8		Covidien, Inc."  S DISTRICT COURT  LICT OF CALIFORNIA
10		
11 12 13 14 15 16 17 18 19 20	CAROL MOORHOUSE and JAMES MOORHOUSE,  Plaintiffs,  vs.  BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC; GENERAL ELECTRIC COMPANY; GE HEALTHCARE, INC.; COVIDIEN, INC.; MALLINCKRODT, INC.; BRACCO DIAGNOSITRICS, INC.; MCKESSON CORPORATION; MERRY X-RAY CHEMICAL CORP.; and DOES 1 through 35  Defendants.	DECLARATION OF THOMAS A. WOODS IN CONSENT TO REMOVAL OF ACTION TO FEDERAL COURT
22	I, Thomas A. Woods, hereby declare:	
24		re true, correct and within my personal
25	knowledge. If sworn as a witness, I could a	• •
26		n of Shook, Hardy & Bacon L.L.P., national
7		Mallinckrodt, Inc." and "Covidien, Inc"
8		
		DECLARATION OF THOMAS A. WOODS RE: REMOVAL
	48682V1	

# **EXHIBIT "D"**

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1
      TUCKER ELLIS & WEST LLP
      MICHAEL C. ZELLERS-STATE BAR NO. 146904
     MOLLIE BENEDICT-STATE BAR NO. 187084
     AGGIE B. LEE-STATE BAR NO. 228332 515 S. Flower Street, 42<sup>nd</sup> Floor
     Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
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     michael.zellers@tuckerellis.com
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 6
     aggie.lee@tuckerellis.com
 7
      Attorneys for Defendant
      BRACCO DIAGNOSTICS INC.
 8
 9
                            UNITED STATES DISTRICT COURT
10
      NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION
11
     CAROL MOORHOUSE and JAMES
                                                    Case No.
     MOORHOUSE,
12
                   Plaintiffs,
                                                    DECLARATION OF AGGIE B. LEE
13
                                                    IN SUPPORT OF DEFENDANT
                                                    BRACCO DIAGNOSTICS INC.'S
14
                                                    CONSENT TO REMOVAL OF
     BAYER HEALTHCARE
                                                    ACTION UNDER 28 U.S.C. §
15
     PHARMACEUTICALS, INC.; BAYER)
                                                    1441(b)
    HEALTHCARE LLC; GENERAL
ELECTRIC COMPANY; GE
HEALTHCARE, INC.; COVIDIEN,
INC.; MALLINCKRODT, INC.;
BRACCO DIAGNOSTICS, INC.;
McKESSON CORPORATION;
MERRY X-RAY CHEMICAL CORP.;
and DOES 1 through 35,
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                   Defendants.
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                       DECLARATION OF AGGIE B. LEE IN SUPPORT OF DEFENDANT BRACCO
                                  DIAGNOSTICS INC.'S CONSENT TO REMOVAL
     1.Aimanage/11255/00006/606119/1
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# **DECLARATION OF AGGIE B. LEE**

I, Aggie B. Lee, declare as follows:

- 1. I am an attorney at law duly authorized to practice before the courts of the State of California and I am an associate with the law firm of Tucker Ellis & West LLP, attorneys for Defendant Bracco Diagnostics Inc. ("BDI"). I have personal knowledge of all of the facts attested to in this declaration and could competently testify thereto if called as a witness in any legal proceeding.
- 2. On March 5, 2008, Plaintiffs Carol Moorhouse and James Moorhouse filed a complaint in the Superior Court of California, San Francisco County captioned as *Carol Moorhouse*, et al. v. Bayer Healthcare Pharmaceuticals, Inc., et al., Case No. CGC08472978.
- 3. On March 6, 2008, BDI's agent for service of process was served with the Complaint, thus removal of this case to federal court is timely.
- 4. BDI consents to removal of this case to the United States District Court for the Northern District of California.
- 5. BDI is incorporated in Delaware and has its principal place of business in New Jersey.

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DECLARATION OF AGGIE B. LEE IN SUPPORT OF DEFENDANT BRACCO DIAGNOSTICS INC.'S CONSENT TO REMOVAL

I declare under penalty of perjury under the laws of the State of California 1 and the laws of the United States of America that the foregoing is true and correct 2 and that this declaration is executed by me on this 31st day of March, 2008, in Los 3 Angeles, California. 4 5 6 7 Of Counsel: Thomas N. Sterchi Patrick Lysaught Paul S. Penticuff Elizabeth McCulley 10 BAKER STERCHI COWDEN & RICE, L.L.C. 11 2400 Pershing Road, Suite 500 Kansas City, MO 64108 12 Telephone: (816) 471-2121 13 Facsimile: (816) 472-0288 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 DECLARATION OF AGGIE B. LEE IN SUPPORT OF DEFENDANT BRACCO DIAGNOSTICS INC.'S CONSENT TO REMOVAL L Aimanage/11255/00006/606110/1

# **EXHIBIT "E"**

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KUTAK ROCK LLP ATTORNEYS AT LAW LOS ANGELES

### declare and say that:

**DECLARATION OF GREG YONKO** 

I, Greg Yonko, declare and say that:

- 1. I am the Senior Vice President of purchasing for McKesson Corporation ("McKesson"), a defendant named in this action. All of the facts stated in this declaration are of my own personal knowledge, and if called as a witness, I would and could competently testify to these facts.
- 2. McKesson is engaged in the business of distributing and selling various medical products. With regard specifically to the product known as gadolinium-based contrast dyes, McKesson's role in the chain of distribution is, and has always been, to sell this product line in various imaging facilities in the same packaging in which it was received from the manufacturer. McKesson does not, and did not, design, manufacture, or administer any gadolinium-based contrast agents. McKesson does not, and did not, design, test, manufacture, or label any gadolinium-based contrast agents.
- 3. With respect specifically to the products known as MRI and MRA machines used in conjunction with gadolinium-based contrast agents, McKesson has, and had no function or role in the chain of distribution of these machines, including but not limited to no role in the designing, testing, manufacturing, or labeling of these products.

I declare under penalty of perjury under the laws of the United States of America and of California that the foregoing is true and correct.

Executed this 19 day of March 2008.

Greg Yorko

4843-8530-9698.1

DECLARATION OF GREG YONKO

CASE NO.

# **EXHIBIT "F"**

# DECLARATION OF LARRY LAWSON

I, Larry Lawson, declare and say that:

- 1. I am employed as President of Merry X-Ray Chemical Corporation ("Merry X-Ray"), a defendant named in this action. I am over the age of 18 and competent to make this declaration. All of the facts stated in this declaration are of my own personal knowledge, and if called as a witness I would and could testify competently to these facts.
- Merry X-Ray is engaged in the business of distributing and selling various medical products. With regard specifically to the product line known as gadolinium-based contrast agents, Merry X-Ray's role in the chain of distribution is, and has always been, to sell this product line to various imaging facilities in the same packaging in which it was received from the manufacturer. Merry X-Ray does not, and did not, design, manufacture, market or administer any gadolinium-based contrast agents. Merry X-Ray does not, and did not, design, assemble or otherwise provide any of the packaging, labels or warnings for any gadolinium-based contrast agents. Merry-X-Ray does not, and did not, design, test, manufacture, label, or market any gadolinium-based contrast agents.
- 3. With respect specifically to the products known as MRI and MRA machines used in conjunction with gadolinium-based contrast agents, Merry X-Ray has, and had, no function or role in the chain of distribution of these machines, including but not limited to no role in the designing, testing, manufacturing, labeling or marketing of these products.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct.

Dated: March 174, 2008

Larry Lawson, Declarant

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KUTAK ROCK LLP ATTORNEYS AT LAW LOS ANGELES

DECLARATION OF LARRY LAWSON